ADVISORY COMMITTEE ON GENETIC TESTING

DRAFT CODE OF PRACTICE FOR GENETIC TESTING OFFERED COMMERCIALLY DIRECT TO THE PUBLIC

Health Departments of the United Kingdom
November 1996

ADVISORY COMMITTEE ON GENETIC TESTING
Department of Health
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8 November 1996

Dear Colleague,

CONSULTATION PAPER - DRAFT CODE OF PRACTICE FOR HUMAN GENETIC TESTING OFFERED COMMERCIALLY DIRECT TO THE PUBLIC

This letter seeks views on the draft Code of Practice for Human Genetic Testing Offered Commercially Direct to the Public prepared by the Advisory Committee on Genetic Testing.

We have known for many years that the absence of, or abnormality in, a single gene can cause serious disease (monogenic disorder). The commonest such disorder in the Caucasian population of the UK is cystic fibrosis: about 1 in 25 of healthy adults carry one defective gene concerned with this condition and the disease itself, which occurs when the individual possesses two defective genes, affects about 1 in 2,500 children. Most of the other 4,000 plus disorders caused by a single faulty gene are much rarer than cystic fibrosis though genetic testing is becoming possible for many of them.

Genetic testing can detect defective genes. Testing can help by detecting the cause of symptoms; or may indicate that a person will develop the symptoms in the future; or that they are a carrier of a condition, so that although they will never be affected, they could have affected children should their partner also be a carrier. There are tests for many inherited monogenic disorders, although we understand that only one genetics testing service - for cystic fibrosis - is currently offered commercially direct to the public in the UK. Tests for genetic susceptibility to common diseases such as cancer, heart disease and diabetes are being developed and an increasing number and range of new tests based on genetics research can be anticipated.

A simple mouth wash may be all that is needed to obtain a specimen for examination in the laboratory - and it is likely that this will be the means used for obtaining samples for those human genetic testing services offered commercially direct to the public. Other testing services may require blood or urine samples.

Human genetic tests differ from most other clinical tests which only involve a single individual, because they may also reveal important information about relatives and can have great impact upon the rest of the family. An adult with no risk of developing an illness may seek advice on the chance of passing on a faulty gene to their children. The genetic consultation needed to explain the consequences of a test result will be different from that needed in many other types of medical test or treatment. Another distinctive feature of some genetic tests is their power to predict the potential future health of the individual in the case of late onset monogenic disease. This possibility to foretell the future with scientific confidence is a totally new feature in diagnosis, and has significance in relation to employment and insurance.

Genetic tests raise ethical questions more complex than those faced in other clinical areas. In addition to the implications for the family as well as the tested individual, the test result may cause anxiety in an otherwise healthy individual. The person tested and possibly their family need to understand, before tests are performed, what the results may mean for them. Confidentiality of information must be protected but the implications for families need to be understood by the person tested.

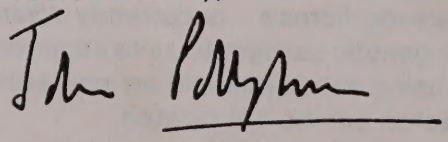
The Government has a public health and consumer protection role to encourage suppliers of human genetic testing services offered commercially direct to the public to work to appropriate criteria. Issues which need to be addressed include which tests are offered to the public, customer consent and the confidentiality of the results. At the same time the Government wishes to ensure that science and industry are encouraged and developed and that the competitiveness of UK business continues to improve. The Government welcomes the contribution such testing services can make to the development, accessibility and understanding of genetics.

The Code of Practice sets out the standards which suppliers of human genetic testing services should seek to meet.

It is important that the Code of Practice is widely understood and accepted by the public, industry and clinicians. This consultation represents an important means of inviting views on our proposals,and I would be grateful for your comments on each of the draft's seven sub-sections. In preparing a draft code the Committee hopes that it will prompt a number of responses. We will take these into account before deciding how best to move ahead.

If you have any comments on the Code of Practice please send them, by 20 December 1996, to Mark Noterman at the address above.

Yours faithfully,



JOHN POLKINGHORNE

DRAFT CODE OF PRACTICE FOR HUMAN GENETIC TESTING OFFERED COMMERCIALLY DIRECT TO THE PUBLIC

Introduction

Advisory Committee on Genetic Testing (ACGT)

ACGT was established, under the Chairmanship of the Reverend Dr John Polkinghorne, past President of Queens' College, Cambridge, in 1996. The Committee's remit covers the whole of the United Kingdom.

The Committee's Terms of Reference are:

(i) to provide advice to Ministers on developments in *genetic testing*;

(ii) to advise on *genetic tests* taking account of ethical, social and scientific aspects;

(iii) to establish requirements, especially in respect of efficacy and product information, to be met by *suppliers* of *genetic tests*.

The Membership of the Committee includes industry and consumer representatives, clinicians, philosophers, academics and scientists (see Annex for full list).

ACGT's Secretariat is provided by the Department of Health, and both that Department and the Department of Trade and Industry send observers to ACGT's meetings.

The Code of Practice

At their first meeting in July 1996 ACGT set up a Sub-Group, chaired by Professor Marcus Pembrey, to prepare this Code of Practice. ACGT consulted widely in late 1996 on the content of the Code, and agreed this final version in **** 1997.

This Code is intended for use by *testing* customers, *suppliers* of human *genetic testing offered commercially direct to the public*, the *testing* laboratories, and general practitioners and other clinicians with an interest.

The contents of this Code do not amend or limit any existing law.

* ~Words in *italics* are described on page 2.

Definitions used in this Code of Practice

Genetic Testing

Testing to detect the presence of or a change in a particular gene.

Genetic Testing Offered Commercially Direct to the Public

Genetic Testing service performed under a commercial contract between a *supplier* and a member of the public.

Testing

Genetic testing service offered commercially direct to the public.

Supplier

The provider of a human genetic testing service offered commercially direct to the public.

Customer

A member of the public contracting with a supplier for human genetic testing.

Recessive Disorders

Those disorders, where for a person to be affected, a defective gene has to be inherited from both parents who are usually unaffected carriers of that gene. Common such disorders in the UK are cystic fibrosis, sickle cell disease and thalassaemia.

Dominant Disorders

Those disorders where inheritance of a defective gene from one parent only can be sufficient to be affected. Common such disorders in the UK include Huntington's Disease, polycystic kidney disease and neurofibromatosis.

This Code is not intended to cover genetic testing provided in the context of professional medical practice.

DRAFT CODE OF PRACTICE

1. Equipment and Reagents

All equipment and reagents for *testing* should be manufactured and maintained to an appropriate level and provide assured levels of accuracy and reliability.

ACGT notes that some sampling devices may be required to comply with relevant UK Regulations and European Directives. ACGT recommends that the essential quality requirements set out in The General Product Safety Regulations 1994 and the European Parliament and Council Directive on In Vitro Diagnostic Medical Devices are the minimum adopted [*Note: the second sentence to be used if the Directive is in force when the Code of Practice is published*].

2. Testing Laboratories

All laboratories offering *genetic testing* services should be appropriately staffed and equipped, and should participate in an accreditation scheme.

ACGT recommends that all laboratories be accredited under an appropriate scheme of quality assurance, and where available to participate in an externally operated scheme of quality assurance. Such accreditation is a fundamental aspect of good practice and ACGT believes that this should be followed in all laboratories offering *genetic testing,* not only those offering *testing* direct to the public.

3. Confidentiality and Storage of Samples and Records

Suppliers* should keep *customer* data confidential. *Suppliers* should inform customers of their procedures for ensuring confidentiality of data and their procedures for storage and disposal of samples and records. Testers should not pass on, or resell, any samples or other customer information to third parties without specific written approval of the *customer.

ACGT expects that the principles set out in Health Departments Guidance (eg the Department of Health's "The Protection and Use of Patient Information") are applied. ACGT expects that all staff with access to individual *customer* samples or data should be bound by a code of confidentiality. ACGT expects samples only to be tested only as contracted. Additional testing, genetic or non-genetic, should not be performed on samples or derivatives of samples without the *customers* specific consent. ACGT recommends that testers should retain test samples for a minimum

of three months, and individual *customer* data for a minimum of twelve months from the notification of the result to the *customer*. ACGT encourages *suppliers*, with the explicit consent of *customers* and ensuring confidentiality, to record suitably anonymised genetic data for future use.

4. What testing may be offered?

Genetic testing offered commercially direct to the public **should be restricted to those tests which determine carrier status for inherited *recessive disorders* in which carrier status carries no significant direct health implications for the carrier individual (eg cystic fibrosis).**

Genetic testing **for inherited dominant and X-linked disorders, for adult onset genetic disorders regardless of inheritance and for the genetic component(s) of multifactorial or acquired diseases raises issues beyond this Code of Practice. In these cases ACGT asks *suppliers* to present *testing* proposals to the Committee for comment.**

ACGT considers that carrier *testing* for inherited childhood onset *recessive disorders* should be available without comment from the Committee, but asks *suppliers* to notify the Committee of their proposal to offer such *testing.* ACGT asks *suppliers* to ensure that the implications of offering *testing* to women who may be pregnant are considered and that appropriate information is provided to *customers* who may be pregnant or planning pregnancy. ACGT recommends that *suppliers* should ask *customers* to provide any known family history of the disorder to be tested, and also advise potential *customers* with a known family history of the disorder to consult their general practitioner before *testing.*

Suppliers planning to offer *testing* for any other disorder directly to the public should, on a voluntary basis, request comment from ACGT prior to introduction. In the near future ACGT will issue further guidance on the information that it would expect *suppliers* to provide when submitting such testing proposals to the Committee.

5. Information and Genetic Consultations for Customers

5.1 Information.

Suppliers **should provide adequate information to *customers* giving details of the tested condition, the nature of the test, its accuracy and the significance and use of results. *Suppliers* should consult widely on the details included in *customer* information. *Suppliers* should provide *customers* with information on appropriate professional and voluntary bodies (after seeking their approval) offering support to those with positive test results.**

ACGT suggests that *suppliers* should work with appropriate professional and voluntary bodies when developing advertising and other *customer* information materials. ACGT recommends that *suppliers* apply the principles of the current advertising regulations to their advertising and other *customer* information materials. ACGT asks suppliers to provide the potentially pregnant with specific information on the implications of *testing* and test results. ACGT asks that *suppliers* provide *customers* with information on any legal, safety and insurance implications that may arise from a test result.

ACGT recommends to *suppliers* the principles set out in the Gene Therapy Advisory Committee's booklet "Writing Information Leaflets for Patients Participating in Gene Therapy Research", and intends to prepare similar guidance for "Writing Information Leaflets for *Customers* of Human *Genetic Testing Offered Commercially Direct to the Public*".

5.2 Genetic Consultation.

***Suppliers* should give *customers*, or their medical representative, opportunities for pre and post test genetic consultation. Consultations should be provided by suitably qualified and experienced professionals.**

6. Involvement of General Practitioners

***Customers* of human *genetic testing* offered direct to the public should be asked for their written consent to the disclosure of the test result and appropriate explanation to their general practitioner and if it is forthcoming, for the name and address of the practice. If the *customer* has consented *suppliers* should send a copy of the test result direct to the general practitioner. In addition *suppliers* should send all *customers* two copies of the test result suggesting that one is given to the general practitioner for inclusion in their health record.**

ACGT consider that test results are an important part of health records and that *customers* should be encouraged to ensure that their results are, with their consent, copied to their general practitioner. ACGT hope that those *customers* who fail to provide the general practitioner's details on the application form will pass on the second copy of the results.

7. Testing of Children

Genetic testing services offered direct to the public should not be offered commercially to those under the age of 16.

In cases where those under 16 wish to be tested, or a person or person(s) with parental responsibility wishes for someone under 16 to be tested, the following principles should be recognised:

- Persons under the age of 16 have the right to be informed about being tested and to express their views freely. Those views should be given due weight in accordance with the age and maturity of the child.

- Persons under the age of 16 should not be tested pre-symptomatically for adult-onset conditions for which there are no clinical treatments.

- If the person under the age of 16 does not have the capacity to make an informed decision a person or person(s) with parental responsibility has/have the right to make an informed choice on whether or not to have that person tested for childhood-onset conditions.

- If the person under the age of 16 does not have the capacity to make an informed decision a person or persons with parental responsibility has/have, after suitable genetic consultation, the right to make an informed choice about whether or not to have that person tested for carrier status.

Draft 5.11.96

ANNEX

ıbers of the Advisory Committee on Genetic Testing (ACGT)

Reverend Dr John Polkinghorne - Chairman	Past President of Queens' College, Cambridge.
Professor Kay Davies	Department of Biochemistry, Oxford.
Professor Robin Downie	Department of Philosophy, University of Glasgow.
Professor John Durant*	Assistant Director, The Science Museum, South Kensington.
Professor Peter Harper	Professor & Consultant in Medical Genetics, Cardiff.
Dr Hilary Harris*	General Practitioner, Manchester.
Professor John Harris	Professor of Bioethics & Applied Philosophy, University of Manchester.
Miss Wendy Johnston	Genetic Health Visitor, Belfast City Hospital Trust.
Mrs Christine Lavery	Society for Mucopolysaccharide Diseases and founding trustee of the Genetic Interest Group.
Dr Sally Macintyre	Director, MRC Medical Sociology.
Mr Matthew Parris	The Times.
Professor Marcus Pembrey*	Mothercare Professor of Paediatric Genetics, Institute of Child Health.
Dr Sultana Saeed	Formerly Lecturer in Law, University of London.
Mr Philip Webb*	General Manager, Zeneca Diagnostics, Abingdon, Oxfordshire.

ıbers of the Code of Practice Sub-Group.